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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,024	07/22/2003	Tomio Kimura	03350CIP/HG	9538
1933	7590	10/19/2004	EXAMINER	
FRISHAUF, HOLTZ, GOODMAN & CHICK, PC 767 THIRD AVENUE 25TH FLOOR NEW YORK, NY 10017-2023			HUANG, EVELYN MEI	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/625,024

Applicant(s)

KIMURA ET AL.

Examiner

Evelyn Huang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-69 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Upon reconsideration, the restriction requirement under 35 U.S.C. 121 is restated as follows:

- I. Claims 24, 36-46, and claims 1-23, 25-35, 47, 48, 49 in part, drawn to a compound wherein A is pyrazole, classified in class 548, subclass 373.1, and the composition thereof.
- II. Claims 1-23, 25-35, 47, 48, 49 in part, drawn to a compound wherein A is imidazole, classified in class 548, subclass 311.1, and the composition thereof.
- III. Claims 1-22, 25-34, 48, 49 in part, drawn to a compound wherein A is isoxazole, classified in class 548, subclass 240, and the composition thereof.
- IV. Claims 1-22, 25-34, 48, 49 in part, drawn to a compound wherein A is isothiazole, classified in class 548, subclass 206, and the composition thereof.
- V. Claims 1-22, 25-34, 48, 49 in part, drawn to a compound wherein A is furan, classified in class 549, subclass 448, and the composition thereof.
- VI. Claims 1-22, 25-34, 48, 49 in part, drawn to a compound wherein A is thiophene, classified in class 549, subclass 59, and the composition thereof.
- VII. Claims 1-22, 25-34, 48, 49 in part, drawn to a compound wherein A is benzene, class and subclass various dependent on the species elected, and the composition thereof.
- VIII. Claims 1-22, 25-34, 48, 49 in part, drawn to a compound wherein A is pyridine, classified in class 546, subclass 276.4, and the composition thereof.
- IX. Claims 1-22, 25-34, 48, 49 in part, drawn to a compound wherein A is pyridazine, classified in class 544, subclass 238, and the composition thereof.
- X. Claims 1-22, 25-34, 48, 49 in part, drawn to a compound wherein A is pyrimidine, classified in class 544, subclass 333, and the composition thereof.

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- XI. Claims 50-64, drawn to multiple methods of use. Class 514, subclass various dependent on the species elected. If this group were elected, election of a single disease and a species compound is required. Further restriction would be required.
- XII. Claims 65, 66, 69, drawn to an intermediate compound of formula (53) and its process of making, class and subclass various dependent on the species elected.
- XIII. Claims 67, drawn to a process for making the intermediate compound of formula (48), class and subclass various dependent on the species elected.
- XIV. Claim 68, drawn to a process for making the intermediate compound of formula (I), class and subclass various dependent on the species elected.

The inventions are distinct, each from the other because of the following reasons:

The compounds of Groups I-X are structurally, chemically and patentably distinct. They have acquired a separate status in the art as shown by their different classification. A reference anticipating a pyrazole compound of Group I would not render obvious the imidazole of Group II, the isoxazole of Group III, the isothiazole of Group IV, the furan of Group V, the thiophene of Group VI, the benzene of Group VII, the pyridine of Group VIII, the pyridazine of Group IX or the pyrimidine of Group X. The search is not co-extensive and is therefore burdensome. Since the search required for one group is not required for the other groups of inventions, restriction for examination purposes as indicated is proper.

Inventions I-X and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed in Group I can be used in a materially different processes, such as in the treatment of inflammation, pain, septicemia, arthritis etc.

Inventions I-X and XII are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate

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product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as pharmaceuticals and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The process of Group XIII is for making a different intermediate compound. The process of Group XIV is for making another intermediate compound.

These inventions are distinct for the reasons given above and they have acquired a separate status in the art because of their recognized divergent subject matter. Since the search required for one group is not required for the other groups of inventions, the search is not coextensive and is therefore burdensome. Restriction for examination purposes as indicated is proper.

2. Applicant is advised that the reply to this requirement to be complete must ***include an election of the invention and a single compound*** to be examined even though the requirement be traversed (37 CFR 1.143).
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found

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allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

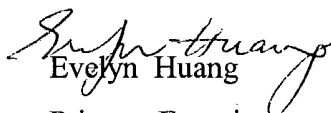
Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Evelyn Huang', is written over the printed name.

Primary Examiner

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